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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,526	01/23/2007	Judith Boston	JUBOS.001NP	6984

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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07/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/574,526	Applicant(s) BOSTON, JUDITH	
	Examiner FRANK I. CHOI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 133-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 133-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) needs to be filed which in addition to identifying this application by application number and filing date also includes the date the preliminary amendment was filed, i.e. 3/31/2006. See MPEP §§ 602.01 and 602.02.

The Applicant filed a preliminary amendment on 3/31/2006 in which the PCT/US2004/032375 application was incorporated by reference and all other references cited in the application were incorporated by reference. The Specification and drawings do not contain said incorporation by reference statements. Since the Application was filed after 9/21/2004, the preliminary amendment is part of the disclosure as it was present at the time the application was filed. However, where a preliminary amendment contains subject matter not otherwise included in the specification and drawings of the application, the applicant must provide a supplemental oath or declaration under 37 CFR 1.67 referring to such preliminary amendment. See MPEP Section 608.04(b) [R-3]. The Application contains additional subject matter because mere citation to an application or other reference does not serve to incorporate the subject matter of said reference. Since the application and other references are now incorporated by reference, the preliminary amendment added subject matter that was not otherwise included in the Specification and drawings.

The Applicant has duly considered the Applicant's arguments but deems them unpersuasive.

While it is true the preliminary amendment was not entered, said preliminary amendment included the reference to the related applications. If the correction to the preliminary amendment and oath is not made than the Applicant's priority claim is invalid.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 133-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification does not enable methods of medical treatment and compositions for medical treatment containing tetrameric oxygen (O4). Claims 133-146, do not explicitly state that the oxygen is tetrameric oxygen. However, since the Specification and claims as originally filed indicated that the oxygen was tetrameric oxygen, the enablement rejection applies to the extent the scope of claims 133-146 include tetrameric oxygen.

The nature of the invention:

The invention is directed to method of using as a medical treatment and compositions for use in medical treatment containing tetrameric oxygen (O4).

The state of the prior art and the predictability or lack thereof in the art:

There does not appear to be any prior art directed to the use of tetrameric oxygen (O4) as claimed. Further, there is insufficient evidence to establish that O4 exists, much less be prepared

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and/or isolated. At most, the existence of O₄ has been theorized, however, the disclosed stability is in the realm microseconds. As such, even if O₄ does exist, because the molecule would only exist for microseconds, there does not appear to be any practical method of preparing a composition which can be used to treat a given condition. See Schroder, pp. 573-574.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification alleges that there is a product containing O₄ in an aqueous solution, however, said assertion is suspect in view of the above.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim the use of tetrameric oxygen. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to show that O₄ exists and prepare compositions that would enable O₄, if it does exist, to be stable enough to be used in medical treatment.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant submits the Sherwood reference, however, the Sherwood reference does not disclose tetrameric oxygen (O₄) but an anion (O₄⁻). The Applicant present no evidence that O₄⁻ is equivalent to O₄. Further, there is nothing in the Sherwood reference which indicates that the anion species as prepared in the Sherwood process could be incorporated into an aqueous solution for use as a pharmaceutical.

Claims 133-146 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims do not recite the presence of tetrameric oxygen (Although claim 135 refers to Sante Oxygen ®, the same is a trademark and refers to the source not to the product and thus cannot be interpreted as a recitation of tetrameric oxygen in the claim) However, Paragraph 0009 of the Specification, clearly states that “The invention therefore provides methods, apparatuses and systems for delivering tetrameric oxygen to tissues”. As such, there is no indication that the inventors, at the time the application was filed, contemplated an invention which is devoid of tetrameric oxygen.

The Applicant has duly considered the Applicant's arguments but deems them unpersuasive.

The Examiner is not asserting that the compositions do not contain O₂ (since they are exposed to air there is no doubt there is some amount of dissolved oxygen contained therein). The Examiner is asserting that based on the Specification and claims as originally filed, the claims cannot include with their scope an embodiment that does not include tetrameric oxygen. The Applicant's citation to paragraph 0011 does not overcome the rejection as paragraphs 0002 and 0009 clearly indicate that tetrameric oxygen is a critical component of the invention.

Claims 133-149 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing oxygen levels in a tissue of an individual with composition which is a gas and contains about 10% to about 25% free available oxygen by volume, does not reasonably provide enablement for any other formulation. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a method of increasing oxygen levels in a tissue of an individual by administering a composition which comprises between about 10% and about 25% free available oxygen by volume.

The state of the prior art and the predictability or lack thereof in the art:

The prior art does not disclose a composition which comprises between about 10% and about 25% free available oxygen by volume other than as gas. Supersaturated aqueous solutions of dissolved oxygen under pressure in bottles are on the order of low hundreds of ppm or less, which oxygen begins to escape into the atmosphere as soon as the bottle is opened. See e.g. Nestle et al., page 3363, Table 1, Page 3364, Fig. 3. As such, there is insufficient evidence to support the assertion that the disclosed aqueous tetrameric oxygen solution or the other disclosed formulations would contain a concentration of oxygen of about 10% by volume to about 25% by volume which equates to about 100,000 ppm to about 250,000 ppm of dissolved oxygen. As such, predictability in the art appears to be low as to suitable dosage forms which are not gases.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification does not provide any guidance as to a composition which comprises between about 10% and about 25% free available oxygen by volume as the "oxygen" identified in the Specification is tetrameric oxygen which as indicated above is not enabled by the Specification. Further, the "composition" disclosed is an aqueous solution which purportedly

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contains 25% dissolved oxygen as tetrameric oxygen and is a dietary supplement (Specification, paragraph 0010). Paragraph 0010 indicates that the term “composition” wherever set forth in the Specification refers to the composition disclosed in paragraph 0010 of the Specification.

However, the Specification does not disclose how the composition which is an aqueous solution can be delivered as gel, solid, semi-solid, paste, lotion, mists, spray, foams, suppositories, emulsion, sustained release form, transdermal patch or body wrap and still retain the purported amount of dissolved tetrameric oxygen and does not disclose how a dietary supplement can be made suitable as an injection.

The breadth of the claims and the quantity of experimentation needed:

The Claims are broad in that they claim a free available oxygen concentration of about 10% to about 25% by volume which includes formulations other than gases. As such, one ordinary skill in the art would be required to do undue experimentation in order to formulate the described aqueous solution of tetrameric oxygen into other formulations while retaining the purported amount of free available oxygen concentration by volume.

The Examiner had duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant does not appear to address this enablement rejection. It is not solely based on the argument that O4 cannot practically be used as a pharmaceutical but also on the fact that physically it is just not possible to prepare a product which is not a gas which maintains a concentration of oxygen (tetrameric or O₂) of about 10 to about 25% by volume.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 135 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 135 contains the trademark/trade name Sante Oxygen ® (The Examiner notes that the Applicant has misspelled it as “Santee”). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a product and, accordingly, the identification/description is indefinite. The Applicant argues that because claim 133 (on which claim 135 is dependent describes Sante Oxygen ® that this makes the claim definite. However, whether or not claim 133 describes Sante Oxygen ® is immaterial (The examiner notes that claim 133 does not as the product contains more than an aqueous solution of about 10 to about 25% free oxygen. The issue is whether the trademark is being used to represent the product. It is therefore the claim is indefinite.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
July 8, 2010

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616